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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,733	02/11/2004	Bernhard Goller	21654	2812
151	7590	06/14/2006	EXAMINER	
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			SHEN, BIN	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/776,733

Applicant(s)

GOLLER ET AL.

Examiner

Bin Shen

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1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Specification**

1. The use of the trademark "FluoSpheres" has been noted on page 10 in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The specification is objected to for inappropriate notation of an internet address. On the last line of page 7, an internet address is cited in an unacceptable form. See M.P.E.P. 707.05(e) for the acceptable notation of an internet address.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is rendered vague and indefinite by the phrase "the number of latex particles and cells is measured by differential side scatter light and forward scatter light". It is not clear "the number of latex particles and cells" are measured by both differential

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side scatter light and forward scatter light or they are measured by the two kinds of scatter lights respectively. Furthermore, claim 4 recite the limitation "cells" (dead? alive? or total?), it would be clearer if applicant use "cell sample".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson et al. (Cancer Res. 1986).

Stevenson et al. teach simultaneous measurements of macrophage-induced cytostasis (cells arrested read on as proliferation inhibition) and cytotoxicity of EMT6 cells by flow cytometry (see abstract). Proliferating mammalian cell EMT6 (mammary tumor cell) is cultured with activated and nonactivated (read on as two different predetermined concentrations) macrophages (substance), fixed EMT6 cells (read on as total cells) are stained with MI (mithramycin) and viable EMT6 cell are stained under viable conditions with vital dye HO, predetermined amount of latex particles are added to the cell suspensions, flow cytometric analysis with single and dual laser analysis (read on as a detection apparatus using a combination of scattered-including forward and side scatter light, and fluorescent light) are performed to determine the cell proliferation activity and toxicity of macrophages (see

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Materials and Methods and Chart 1). The number of HO-stained viable cells is determined by fluorescence light emitted from 420-490nm (read on as at first wavelength); the number of total cells (MI-stained) per volume is determined by fluorescence light emitted from 495-520nm (read on as at second wavelength); the number of beads per volume is determined by fluorescence light emitted above 550nm (read on as at third wavelength) (see page 100, left panel, 7<sup>th</sup> and 8<sup>th</sup> paragraph). The cell sample is present as a cell suspension (see abstract). The fixed EMT6 cells (read on as dead cells) are stained with MI (page 100, left panel, 4<sup>th</sup> paragraph) and the number of latex particles and cells is measured by flow cytometry as described above.

Therefore, the cited reference is deemed to anticipate the instant claims above.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al. in view of Ferlini et al. (Pharmacology & Toxicology 2001, 89, 231-236).

Stevenson et al. teach what is above.

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Stevenson et al. do not teach the use of human CD34+ progenitor cells and the automation (use of multiple device and automated pipetting) of the method.

Ferlini et al. teach a new method to evaluate toxicity of antitumour agents with human CD34+ progenitor cells (see abstract) and the progress to standardize a "high throughput method" (flow cytometric analysis apparatus by automate pipetting) to assess cytotoxic effects in microplates (multiple device) minimizing time required for the analysis (page 235, right panel, lines 13-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Stevenson et al. by using human CD34+ progenitor cells and automate the flow cytometric analysis apparatus as taught by Ferlini et al. One would have been motivated to use human CD34+ progenitor cells and automate the flow cytometric analysis apparatus to improve Stevenson's method because Ferlini et al. teach two advantages of using human CD34+ progenitor cells to screen for toxicity of new antitumour agents (see page 235, left panel, third paragraph), and would reasonably have expected success in view of Stevenson's teaching that proliferation inhibition and cytotoxicity can be simultaneous measured in proliferating mammalian cell by flow cytometry and Ferlini's teaching of using human CD34+ progenitor cells to screen for new antitumor agent with maximal ratio between activity and toxicity, and that the method is performed in liquid phase allows its optimization in a conventional "high throughput system".

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable

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expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

6. No claim is allowable.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the

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problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.



**MICHAEL MELLER  
PRIMARY EXAMINER**

*B Shen*

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